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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,562	12/05/2003	Thomas Leon	152-55CIP	2009

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Galgano & Burke
Suite 35
300 Rabro Drive
Hauppauge, NY 11788

EXAMINER	
SUTTON, DARRYL C	
ART UNIT	PAPER NUMBER
1612	

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08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,562	LEON ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the request for continued Examination filed 07/14/2008. All previous rejections have been withdrawn unless indicated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gould et al. (U.S. 3,641,237) in view of Acharya (U.S. 5,686,094).

Gould et al. teach a controlled zero-order release system for pharmaceutically active compounds (column 1, lines 49-50). The invention can be used in human, or veterinary therapy, e.g. to treat dogs (column 5, lines 33-35).

Gould et al. do not teach a pliable film with a moisture content of about 4%-7%, or not greater than 15% by weight. Gould et al. do not teach the administration schedule of instant claims 7-13.

Acharya teaches a polymeric delivery system which is formed by a polycarbophil type composition with an active agent, optionally in the presence of water and other

cosolvents. The composition is useful for oral controlled or sustained release of active agents that are drugs, cosmetic agents, and nutritional agents; the system may contain substantially any medicinal or cosmetic agent (Abstract, column 1, lines 8-10, column 3, lines 25-30, column 4, lines 32-37). The composition is an intimate mixture, which means the components are mixed substantially uniformly so that none of those components are localized (column 12, lines 64-67, column 13, lines 1-3). The present invention provides several advantages and benefits, including an improved composition and method for the controlled release of an active composition, such as a pharmaceutical, to oral skin or mucosa over a period of time (column 3, lines 22-27). The composition can be provided as a three-dimensional structure such as a film (column 10, lines 2-5). The resulting matrix of polycarbophil, active ingredient and water may be formed by cutting into pieces of appropriate size and shape; and can be dried to any degree of hardness and moisture content (column 5, lines 20-25). The polycarbophil component may be interacted with water, which may be mixed with other cosolvents e.g. glycerol, propylene glycol, or polyethylene glycol (column 12, lines 17-22). The controlled release rate is dependent upon the structure of the matrix which may be modified with water, polar or nonpolar solvents; and by varying their amounts and the inclusion of other components, including hydrocolloids such as hydroxypropyl cellulose (column 5, lines 44-53). The desired level of controlled or sustained release will vary, depending upon the ratio of the components employed, the physical state of the components of the particular active composition, the method of incorporation, the order of mixing, and the like (column 12, lines 43-48). The pharmaceutical and

cosmetic compositions are substantially non-toxic to animals in which or on which they are placed; and when contacted with and adhered to the skin or mucosa, the compositions cause no whitening or blistering effects due to the composition (column 6, lines 62-64). It is relatively an easy laboratory task to formulate a series of controlled release compositions containing a range of active compositions to determine the effective amount of such an active composition for a particular composition of the invention (column 10, lines 44-52). The composition is then used to contact an area of skin or mucous membrane to be treated, for a sufficient period of time to allow a therapeutically effective amount of active composition to be released (column 3, lines 37-41). Active agents include penicillin (col. 7, lines 60-68), an active agent disclosed by the instant specification.

Acharya does not teach a method of treating a non-human mammal comprised of providing a film comprised of a veterinary agent and with a moisture content of about 4%-7%. Acharya does not teach the administration schedules of instant claim 7.

At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the veterinary therapy method of Gould et al. to include the film of Acharya et al. motivated by the desire to provide improved oral controlled release of the active agents as taught by Acharya et al. It would have been obvious to use a finger as an insert device to contact and to adhere the film to the skin or mucous membrane.

In regards to claims 8-10, the prior art reference teaches that the films may be adhered long enough to release effective amounts of active agent, but that the compositions can vary in the amounts of active ingredients; therefore it would have

been obvious to provide multiple daily administrations of the invention which contain active ingredients in the lower range of effective amounts to provide dosages equivalent to the total effective amount of active ingredient. The multiple daily administrations would also be a plurality of times during a single week, and during a single month.

In regards to claims 1 and 4-6, where the general teaching of a claim is disclosed in the prior art, it is not inventive to determine the optimum or workable ranges through routine experimentation. See MPEP 2144.05, II. Optimization of Ranges. Therefore at the time of the invention it would have been obvious to determine the optimum or workable ranges of moisture content for the film.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612